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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/680,288

10/08/2003

Toby Freyman

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4217

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KENYON & KENYON LLP  
1500 K STREET N.W.  
SUITE 700  
WASHINGTON, DC 20005

EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

02/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/680,288	<b>Applicant(s)</b> FREYMAN ET AL.	
	<b>Examiner</b> Victor X. Nguyen	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 6-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 22-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The request filed on 12/20/2007 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/680,288 is acceptable and a RCE has been established. An action on the RCE follows.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In **claim 2**, the disclosure does not describe “a distal outlet in communication with the lumen, and the orientation of the catheter distal outlet relative to the anatomical reference is to be determined based on a predetermined orientation of the catheter distal outlet relative to the reference portion of the catheter...” and yet only on page. 7 of applicant’s specification (submitted on 10/8/2003), lines 6-10 does mention “and the orientation of distal orifice 3 is pointing relative to the strain gauges is also known, the orientation of distal orifice 3 relative to the anatomical reference may be ascertained”. However, it does not disclose that this distal outlet in communication with the lumen, and the orientation of the catheter distal outlet relative to the anatomical reference is to be determined based on a predetermined orientation of the catheter distal outlet relative to the reference portion of the catheter... as is now claimed. Clarification is requested.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-2, 24 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shlomo (6,272,371). Shlomo discloses a bend responsive catheter having the limitations as recited in the above listed claims, including: a catheter 20 has a tube wall (the tube wall occurs along the bend segment of element 20) defining a lumen, a plurality of tube wall bending indicators at 28,30 locates within the catheter wall which is capable of becoming curved when the catheter is at a target site within the patient's body, where the plurality of tube wall bending indicators are able to provide an indication of the tube wall bending relative to the anatomical reference (see col. 6, lines 19-52), where the catheter further comprises a distal outlet at the left side of element 28 in communication with the lumen, and where the catheter is able to view by radiopaque under x-ray fluoroscopy see( col. 2, lines 29-34)

Claim1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist (5,228,441). Lunquist discloses a torque catheter having the limitations as recited in the above listed claim, including: a catheter 21 has a tube wall (the tube wall occurs along the bend segment of element 22) defining a lumen, a plurality of tube wall bending indicators at 76,77 locates at the catheter wall which is capable of becoming curved when the catheter is at a target site within the patient's body, where the plurality of tube wall bending indicators is able to provide an

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indication of the tube wall bending relative to the anatomical reference (see col. 6, lines 54-67, col. 8, lines 4-25).

Claims 5,25-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hecke(5,448,989). Hecke discloses an endoscopic instrument having the limitations as recited in the above listed claim, including: a catheter 1 has a tube wall (the tube wall occurs along the bend segment of element 5) defining a lumen, a plurality of tube wall bending indicators at 10,11 locates at the catheter wall which is capable of becoming curved when the catheter is at a target site within the patient's body, where the plurality of tube wall bending indicators is able to provide an indication of the tube wall bending relative to the anatomical reference (see figs. 2,4 and 7), and where the tube wall bending indicators comprises a plurality of rods movably embedded in the catheter wall at best seen in fig. 2, where the rods are able to provide the indication of the tube wall bending by changing an amount of protrusion relative to the proximal end of the catheter in accordance with an amount of the tube wall bending in the vicinity of the rod (see col. 6, lines 1-11), and where the device further has a panel at 6 (fig. 4), where the rods are routed through the side tube (fig. 2). It is noted that the device 1 of Hecke would inherently use imaging under x-ray to view the device.

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shlomo (6,272,371) in view of Moberg et al (5,628,777).

Shlomo discloses the invention substantially as claimed, but Shlomo is silent regarding the tube wall comprises a plurality of strain gauges.

Moberg teaches a tube wall having a plurality of strain gauges (see col. 15, lines 18-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shlomo by making a tube wall having a plurality of strain gauges as taught by Moberg in order to determine the dimensional different between the tube wall. As to claim 22, Shlomo discloses the device further has signal wires 34 which are transmitted to the orientation display via the signal wires

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen

Examiner

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VN

2/8/2008

/ (Jackie) Tan-Uyen T. Ho/  
SPE of Art Unit 3773

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